1271.90 Are there exceptions from the requirement of determining donor eligibility, and what labeling requirements apply?

Subpart D—Current Good Tissue Practice

1271.145 Prevention of the introduction, transmission, or spread of communicable diseases.
1271.150 Current good tissue practice requirements.
1271.155 Exemptions and alternatives.
1271.160 Establishment and maintenance of a quality program.
1271.170 Personnel.
1271.180 Procedures.
1271.190 Facilities.
1271.195 Environmental control and monitoring.
1271.200 Equipment.
1271.210 Supplies and reagents.
1271.215 Recovery.
1271.220 Processing and process controls.
1271.225 Process changes.
1271.230 Process validation.
1271.250 Labeling controls.
1271.260 Storage.
1271.265 Receipt, predistribution shipment, and distribution of an HCT/P.
1271.270 Records.
1271.290 Tracking.
1271.320 Complaint file.

Subpart E—Additional Requirements for Establishments Described in § 1271.10

1271.330 Applicability.
1271.350 Reporting.
1271.370 Labeling.

Subpart F—Inspection and Enforcement of Establishments Described in § 1271.10

1271.390 Applicability.
1271.400 Inspections.
1271.420 HCT/Ps offered for import.
1271.440 Orders of retention, recall, destruction, and cessation of manufacturing.

AUTHORITY: 42 U.S.C. 216, 243, 263a, 264, 271.

SOURCE: 66 FR 5466, Jan. 19, 2001, unless otherwise noted.

Subpart A—General Provisions

§ 1271.1 What are the purpose and scope of this part?

(a) *Purpose.* The purpose of this part, in conjunction with §§ 207.20(f), 210.1(c), 210.2, 807.20(d), and 820.1(a) of this chapter, is to create a unified registration and listing system for establishments that manufacture human cells, tissues, and cellular and tissue-based products (HCT/P's) and to establish donor-eligibility, current good tissue practice, and other procedures to prevent the introduction, transmission, and spread of communicable diseases by HCT/P's.

(b) *Scope.* (1) If you are an establishment that manufactures HCT/P's that are regulated solely under the authority of section 361 of the Public Health Service Act (the PHS Act), this part requires you to register and list your HCT/P's with the Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research and to comply with the other requirements contained in this part, whether or not the HCT/P enters into interstate commerce. Those HCT/P's that are regulated solely under the authority of section 361 of the PHS Act are described in § 1271.10.

(2) If you are an establishment that manufactures HCT/P's that are regulated as drugs, devices and/or biological products under section 351 of the PHS Act and/or the Federal Food, Drug, and Cosmetic Act, §§ 207.20(f) and 807.20(d) of this chapter require you to register and list your HCT/P's following the procedures in subpart B of this part. Sections 210.1(c), 210.2, 211.1(b), and 820.1(a) of this chapter require you to comply with the donor-eligibility procedures in subpart C of this part and the current good tissue practice procedures in subpart D of this part, in addition to all other applicable regulations.

[66 FR 5466, Jan. 19, 2001, as amended at 69 FR 29829, May 25, 2004]

§ 1271.3 How does FDA define important terms in this part?

The following definitions apply only to this part:

(a) *Autologous use* means the implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered.

(b) *Establishment* means a place of business under one management, at one general physical location, that engages in the manufacture of human cells, tissues, and cellular and tissue-based products. ''Establishment'' includes:

(1) Any individual, partnership, corporation, association, or other legal entity engaged in the manufacture of